

Introduction to the Principles and Practice of Clinical Research (IPPCR)

October 14, 2014 – March 9, 2015

All sessions will meet at 5:00 p.m. (Eastern Time) in the Lipsett Amphitheater.

Introduction	
Tuesday, October 14, 2014	Welcome (30 minutes) John I. Gallin, M.D. Director NIH Clinical Center
	History of Clinical Research: A Merging of Diverse Cultures (30 minutes) John I. Gallin, M.D. Director NIH Clinical Center Chapter: 1
Module I: Study Design and Statistics	
Monday, October 20, 2014 Session 1	Unit 1: Choosing a Research Question and Implications for Efficient Clinical Trials (90 minutes) John Powers, III, M.D. Senior Medical Scientist, NCI Frederick Chapter: 19, 25, 29
Tuesday, October 21, 2014 Session 2	Unit 2: Clinical Research from the Patient's Perspective (30 minutes) Jerry Sachs Manager of Guest Services (Retired) Smithsonian Museum of Natural History Chapter: 17 Unit 3: Study Participant Selection (60 minutes) Catherine Stoney, Ph.D. Program Director Prevention and Population Sciences Program, NHLBI Chapter: 2, 13, 19, 26; Please review archived video on Inclusion of Women and Minorities in Clinical Trials (60 minutes) by Miriam Kelty, Ph.D. prior to this lecture

Monday, October 27, 2014 Session 3	Unit 4: Overview of Clinical Study Design (90 minutes) Laura Lee Johnson, Ph.D. Statistician Office of Clinical and Regulatory Affairs, NCCAM Chapter: 19
Tuesday, October 28, 2014 Session 4	Unit 5: Measures (60 minutes) David Luckenbaugh, Ph.D. Biostatistician Experimental Therapeutics and Pathophysiology Branch, NIMH Chapter: 25, 26
Monday, November 3, 2014 Session 5	Unit 6: Design of Epidemiologic Studies (90 minutes) Laura Lee Johnson, Ph.D. Statistician Office of Clinical and Regulatory Affairs, NCCAM Chapter: 18
Tuesday, November 4, 2014 Session 6	Unit 7: Issues in Randomization (90 minutes) Paul Wakim, Ph.D. Team Leader, Biostatistics and Medical Informatics Team Center for the Clinical Trials Network National Institute on Drug Abuse (NIDA) Chapter: 20, 24
Thursday, November 6, 2014 Breakout Session	Breakout Session (60 minutes) Title – TBD Laura Lee Johnson, Ph.D. Statistician Office of Clinical and Regulatory Affairs, NCCAM *Session will be held in FAES Classroom #5 (B1C210)
Monday, November 10, 2014 Session 7	Unit 8: Using Large Datasets for Population-Based Health Research (60 minutes) Leighton Chan, M.D. Chief, Rehabilitation Medicine Department, CC Chapter: 28
Tuesday, November 11, 2014 FEDERAL HOLIDAY Veterans Day	NO LECTURE

Monday, November 17, 2014 Session 8	Unit 9: Designing and Testing Questionnaires (60 minutes) Barbara Stussman, B.A. Survey Statistician, NCCAM Chapter: 25
Tuesday, November 18, 2014 Session 9	Unit 10: Overview of Hypothesis Testing (90 minutes) Laura Lee Johnson, Ph.D. Statistician Office of Clinical and Regulatory Affairs, NCCAM Chapter: 21, 24
Thursday, November 20, 2014 Breakout Session	Breakout Session (60 minutes) Title – TBD Laura Lee Johnson, Ph.D. Statistician Office of Clinical and Regulatory Affairs, NCCAM *Session will be held in FAES Classroom #5 (B1C210)
Monday, November 24, 2014 and Tuesday, November 25, 2014 Recess	Week of Thanksgiving-NO SCHEDULED LECTURES; MAKE-UP LECTURES AS NEEDED
Monday, December 1, 2014 Session 10	Unit 11: Sample Size and Power (90 minutes) Laura Lee Johnson, Ph.D. Statistician Office of Clinical and Regulatory Affairs, NCCAM Chapter: 22, 24
Tuesday, December 2, 2014 Session 11	Unit 12: Conceptual Approach to Survival Analysis (90 minutes) Laura Lee Johnson, Ph.D. Statistician Office of Clinical and Regulatory Affairs, NCCAM Chapter: 23, 24
Thursday, December 4, 2014 Breakout Session	Breakout Session (60 minutes) Title – TBD Laura Lee Johnson, Ph.D. Statistician Office of Clinical and Regulatory Affairs, NCCAM *Session will be held in FAES Classroom #5 (B1C210)

Monday, December 8, 2014 Session 12	Unit 13: Secondary Data/Meta-Analysis (90 minutes) Charles Natanson, M.D. Senior Investigator and Head Anesthesia Section Critical Care Medicine Department, CC Chapter: 27
Tuesday, December 9, 2014 Session 13	Unit 14: Module I Summary and Study Examples (90 minutes) Laura Lee Johnson, Ph.D. Statistician Office of Clinical and Regulatory Affairs, NCCAM Chapter:
Module II: Ethical, Legal, and Regulatory Considerations	
Monday, December 15, 2014 Session 14	Unit 1: Ethical Principles in Clinical Research (60 minutes) Christine Grady, R.N., Ph.D. Head, Section on Human Subjects Research Chief, Bioethics Department, CC Chapter: 2
Tuesday, December 16, 2014 Session 15	Unit 2: FDA Product Regulation (60 minutes) Chris Joneckis, Ph.D. Immediate Office of the Center Director Associate Director for Review Management (Acting) Center for Biologics Evaluation Research, FDA Chapter: 7
Monday, December 22, 2014 through Tuesday, December 30, 2014 Recess	Holiday Recess-NO LECTURES
Monday, January 5, 2015 Session 16	Unit 3: Institutional Review Boards (90 Minutes) Jerry Menikoff, M.D., J.D. Director, Office for Human Research Protections Office of Public Health and Science, DHHS

	Chapter: 5, 6
Tuesday, January 6, 2015 Session 17	Unit 4: Mock IRB (120 minutes) Jerry Menikoff, M.D., J.D. Director, Office for Human Research Protections Office of Public Health and Science, DHHS Chapter: 5, 6
Monday, January 12, 2015 Session 18	Unit 5: Research with Vulnerable Participants (60 minutes) David Wendler, Ph.D. Head, Unit on Vulnerable Populations Section on Human Subjects Research, Bioethics Department, CC Chapter: 2, 5
Module III: Preparing and Monitoring Clinical Studies	
Tuesday, January 13, 2015 Session 19	Unit 1: Data and Safety Monitoring Committees (90 minutes) Pamela Shaw, Ph.D. Assistant Professor Department of Biostatistics and Epidemiology Perelman School of Medicine University of Pennsylvania Chapter: 9
Monday, January 19, 2015 FEDERAL HOLIDAY Martin Luther King Day	NO LECTURE
Tuesday, January 20, 2015 Session 20	Unit 2: Protocol Development (45 minutes) Wendy Weber, N.D., Ph.D., M.P.H. Program Officer Division of Extramural Research, NCCAM Chapter: 29, 32 Unit 3: “Advances in Electronic Protocol Authoring Tools at the NIH” (45 minutes)

	<p>Philip Lightfoot, B.S., B.A. Systems Analysis Department of Clinical Research Informatics, CC</p> <p>Jennifer Morris, B.S. Clinical Protocol Coordinator Office of the Clinical Director, NINDS</p> <p>Chapter: 32</p>
Monday, January 26, 2015 Session 21	<p>Unit 4: Pharmaceutical Development: Management of Projects (60 minutes) Christopher D. Breder, M.D., Ph.D. Clinical Team Leader, Anesthetic Products</p> <p>Chapter: 7, 26, 37, 43</p>
Tuesday, January 27, 2015 Session 22	<p>Unit 5: Evaluation of a Protocol Budget (90 minutes) Phyllis Klein, R.N., CCRC, BSN Director, Regulatory Support and Compliance Washington University in St. Louis</p> <p>Chapter: 33; prior to the lecture review archived video on Development of Manuals of Operating Procedures (90 minutes) by Wendy Weber, N.D., Ph.D., M.P.H.</p>
Monday, February 2, 2015 Session 23	<p>Unit 6: NIH Peer Review Process (90 minutes) Valerie Prenger, Ph.D., M.H.S. Director Office of Scientific Review, NHLBI</p> <p>Chapter: 36</p>
Tuesday, February 3, 2015 Session 24	<p>Unit 7: Design of Case Report Forms (30 minutes) Diane St. Germain, R.N., M.S., C.R.N.P. Nurse Consultant Division of Cancer Prevention, NCI</p> <p>Chapter: 33, 37</p> <p>Unit 8: Data Management in Clinical Trials (30 minutes) Diane St. Germain, R.N., M.S., C.R.N.P. Nurse Consultant</p>

	Division of Cancer Prevention, NCI Chapter: 8
Monday, February 9, 2015 Session 25	Unit 9: Basic Data Representation (60 minutes) Jim Cimino, M.D. Chief Laboratory for Informatics Development, CC Chapter:
Tuesday, February 10, 2015 Session 26	Unit 10: Data & Non-Data Aspects of Quality Control in Clinical Studies (60 minutes) Elizabeth Ness, R.N., MSN Staff Development NCI/CCR Chapter:
Monday, February 16, 2015 FEDERAL HOLIDAY President's Day	NO LECTURE
Tuesday, February 17, 2015 Session 27	Unit 11: Information Resources for Clinical Research (90 minutes) Josh Duberman, M.L.I.S. Informationist/Research Librarian, NIH Library Chapter:
Monday, February 23, 2015 Session 28	Unit 12: Clinical Trial Registration and Results Reporting (90 minutes) Deborah Zarin, M.D. Assistant Director for Clinical Research Projects Lister Hill National Medical Center for Biomedical Communications, NIH Chapter: 15
Module IV: Miscellaneous Topics	
Tuesday, February 24, 2015	Unit 1: Technology Transfer (90 minutes)

Session 29	<p>Bruce Goldstein, J.D. Unit Coordinator Technology Transfer Branch, NCI</p> <p>Chapter: 30, 31</p>
Monday, March 2, 2015 Session 30	<p>Unit 2: Scientific Conduct (60 minutes) James L. Gulley, M.D., Ph.D., F.A.C.P. Director Clinical Trials Group, Center for Cancer Research, NCI</p> <p>Chapter: 4, 12</p>
Tuesday, March 3, 2015 Session 31	<p>Unit 3: Health Disparities Research (60 minutes) Larissa Avilés-Santa, M.D., M.P.H., F.A.C.P., F.A.C.E. Division of Cardiovascular Sciences, NHLBI</p> <p>Chapter: 46</p>
Monday, March 9, 2015 Session 32	<p>Unit 4: Community-Based Participatory Research (30 minutes) Francisco Sy, M.D., Dr PH Director Division of Extramural Activities and Science Programs, NIMHD</p> <p>Chapter: 46</p> <p>Unit 5: Dissemination and Implementation Research (60 minutes) Catherine Stoney, Ph.D. Program Director Prevention and Population Sciences Program, NHLBI</p> <p>Chapter:</p>

Lectures to be Viewed on Archives	
<p>Please view lecture prior to Dr. Catherine Stoney's October 21, 2014 lecture: "Study Participant Selection"</p>	<p>Inclusion of Women and Minorities in Clinical Trials (60 minutes) Miriam Kelty, Ph.D. Special Volunteer Former Associate Director, Extramural Activities, NIA</p> <p>Chapter: 13</p>

Please view lecture prior to Dr. Laura Lee Johnson's December 2, 2014 lecture: "Conceptual Approach to Survival Analysis"	<p>Quality of Life (45 minutes) John Ware, Ph.D. Chief Science Officer John Ware Research Group, Inc.</p> <p>Chapter: 25</p>
	<p>The Clinical Researcher and the Media (45 minutes) John Burklow, M.S. Associate Director for Communications Office of Communications and Public Liaison, NIH</p> <p>Chapter: 16</p>
	<p>Legal Issues in Clinical Research (60 minutes) Carrie Pottker-Fishel, J.D. Attorney Advisor Office of General Counsel, NIH</p> <p>Chapter: 11</p>
Please view lecture after Wendy Weber's January 20, 2015 lecture: "Protocol Development" and prior to Phyllis Klein's January 27, 2015 lecture: "Evaluation of a Protocol Budget"	<p>Development of Manuals of Operating Procedures (90 minutes) Wendy Weber, N.D., Ph.D., M.P.H. Program Director Division of Extramural Research, NCCAM</p> <p>Chapter: 29</p>